Real world data: Additional source for making clinical decisions

International Society for Pharmacoeconomics and Outcome Research has defined real-world data as everything that goes beyond what is normally collected in the phase III clinical trials program in terms of efficacy. It is also conveniently labeled as anything that is not interventional.[1]

Though randomized clinical trials (RCTs) are considered gold standard for establishing efficacy;[2] in general, RCTs use a standardized therapy in a selected group of patients and are typically restricted to evaluating specific discrete interventions one at a time.[3] As such, RCTs fail to assess complex interactions within a study arm, fail to establish continuous relationship and fail to elucidate if the benefits/harms of a treatment are drug specific or mechanistic. As a result, traditional RCTs focuses more on evaluating the efficacy of simple therapies and less on the delivery of care, and it is said that RCTs have internal validity but not external validity. For assessing effectiveness of combinations and for evaluating all these issues in RCTs, many study arms will be required. For example, it would take 32 different study arms to examine all the possible combinations of just five treatments; thus making the costs conduct RCTs that evaluate all these issues prohibitive.[4]

This is where real-world data has a role to play. Many health-care decision makers are developing policies that integrate evidence from different sources. It is importantly being accepted that other sources of data can contribute in important ways to the evidence base (e.g., demonstrating how a drug works in populations not studied in the trial, or relative to another drug not included in the study).[5]

As such in real-world studies, the actual care that patients receive in clinics is recorded. Rather than having strict inclusion and exclusion criteria, all the patients have to be treated, including those with co-morbidities. Such studies generate long term efficacy and safety data along with economic assessment under pragmatic conditions. Moreover, it is possible to compare multiple interventions in such studies.[6] Data source for real-world data can be-supplements to traditional registration RCTs; large, simple trials (known as pragmatic clinical trials); registries; administrative data; health surveys; and electronic health records and medical chart reviews.[5]

Though there are number of issues with collection of real-world data like lack of good quality and sufficiently representative databases in many countries, incomplete databases, presence of many asymptomatic cases in real world (an issue with retrospective observation of data), more chances of bias and confounding in prospective real-world studies (as it is without randomization) etc., real-world data has an important role to play in the evaluation of epidemiology and burden of disease, treatment patterns, compliance, persistence, and health outcomes of different treatments.[1]

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